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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,453	09/13/2000	Steven M. Ruben	PZ038P1	8927

22195 7590 01/09/2003

HUMAN GENOME SCIENCES INC
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ROCKVILLE, MD 20850

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/661,453

Applicant(s)
Ruben et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 9, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-15, 17-36, 39-43, 46-50, 53-57, and 60-73 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10, 13-15, and 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-36, 39-43, 46-50, 53-57, and 60-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-10, 13-15, 17-36, 39-43, 46-50, 53-57, and 60-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' arguments, filed 9/9/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 25 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the specification as filed has revealed that pages 58 and 59 describe SEQ ID NO: 73 but not the specific Methionine lacking truncated versions in instant claims 25 and 31. These versions are therefore NEW MATTER as there is no written basis for them as filed as set forth in the above listed claims. Applicants argue that support for these Methionine lacking truncated versions of SEQ ID NO: 73 is set forth in the specification on page 150, line 31, through page 151, line 6. Consideration of this page 150-151 citation reveals that there is no written disclosure therein of a protein which comprises amino acid residues 2 to 105 of SEQ ID NO: 73. It is noted that a statement is made that "it is well known in the art

that the N-terminal methionine encoded by the translation initiation codon generally is removed with high efficiency from any protein after translation in all eukaryotic cells". The word "generally" in this statement lacks specificity regarding any particular protein or polypeptide. It is also well known in the art that specific proteins are not processed by the removal of N-terminal methionine. The lack of specificity in the quoted statement therefore fails to provide sufficient specific written disclosure for such removal for SEQ ID NO: 73. In order to further support this rejection regarding what is or is not well known in the art, two Arfin et al. references (1995 and 1988) are enclosed herewith which actually document measurements of the a specificity of methionine removal or non removal during eukaryotic protein expression. Two classes of the enzymes which apparently are responsible for methionine removal of nascent polypeptides is described in Arfin et al.(1995). On page 7714, bridging paragraph between the first and second columns, Arfin et al.(1995) describes the removal of initiator methionine as occurring for less than all polypeptides with the first sentence of this paragraph set forth as "Removal of the initiator methionine of nascent polypeptide chains (when it occurs) is...". In the previous paragraph on page 7714 citations are set forth regarding the occurrence of a variety of N-terminal amino acids in mature proteins. One of these reference is Arfin et

al.(1988). Arfin et al.(1988) on page 7980, Figures 1 and 2, depict the variety of N-terminal processing which is observed in eukaryotic protein maturation. Although the N-terminal removal of methionine may occur as defined by the penultimate amino acid as shown in Arfin et al.(1988) in Figure 3, the reference also notes at the bottom of the first column of page 7980 that "additional specifying influences may be found in regions as far as 40 residues from the amino terminus". Although the above discussion only clarifies what is known in the art, it is still maintained that applicants' possession of the specific removal of the N-terminal methionine of SEQ ID NO: 73 is not supported by a general statement which is known to be general and not specific in nature.

LACK OF UTILITY

This has been withdrawn regarding any claim(s) which contain at least one embodiment which is a protein which consists of the amino acids of the entirety of SEQ ID NO: 73 due to the Declaration of Dr. George Komatsoulis regarding the difference in expression of protein which consists of the amino acids of the entirety of SEQ ID NO: 73. Such an embodiment is deemed present in all of the instantly pending claims 24-73.

LACK OF SCOPE OF ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-36, 39-43, 46-50, 53-57, and 60-73 are rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is only supported as to usage regarding a polypeptide consisting only of the entirety of SEQ ID NO: 73, one skilled in the art would not know how to use the claimed invention directed to fragments thereof.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are

considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is no longer directed to the polypeptide consisting of the entirety of the amino acids of SEQ ID NO: 73 per se, but still is maintained against other polypeptides which are fragments thereof or some type of conjugate or fusion protein which is included in the instantly pending claims as they all contain the open claim language wording "comprising" or "comprises". As noted in the previous office action the fragment embodiments may or may not contain recognizable epitopes for assay purposes and no instant disclosure has been set forth as to what conditions etc. are to be utilized for specificity. This issue is appropriate here because the asserted utility which has been also established by said Declaration of Dr. George Komatsoulis is apparently only directed to the detection of expression which is performed generally via appropriate binding assay(s) which need conditions of specificity for their usage.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894.

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The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 8, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER